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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,260	02/13/2002	Domenica Simms	0942.5170001/RWE/ALS	6799
26111	7590	12/19/2005	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			BAUSCH, SARAE L	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 12/19/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/073,260		SIMMS ET AL.	
	Examiner		Art Unit	
	Sarae Bausch		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66 is/are rejected.
- 7) ☒ Claim(s) 1 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/23/2005 has been entered.

Claim Status

2. Currently, claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66 are pending in the instant application. Claim 12-15, 19-20, 26, 32-54, 58-60 and 64-65 have been canceled. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented or are reiterated from the previous office action. Response to arguments follow. This action is Non-FINAL.

3. It is noted that claim 63 does not comply with 37 CFR 1.121, as it does not have the proper marking to indicate the changes that have been made relative to the prior set of claims. In response to this office action, applicant is required to include the appropriate marking to claim 63 to indicate the addition of text that was not previously presented in the last version of the claims. For example, the previous version of claim 63 recited "wherein several samples are processed simultaneously" and this version of claim 63 recites " wherein wherein said second filter is comprised of...", however the claim does not include the previous versions text cross-thorough

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or underlined new text. For the purposes of compact prosecution, the claims are examined as presented in this version of the claims, however applicant is required to make the appropriate markings to claim 63 in the next action.

Withdrawn Rejections

4. The rejections of claims 19 and 24, under 35 U.S.C. 103(a), made in section 10, page 7-8 of the previous office action, is withdrawn in view of the amendment to the claims.

5. The rejections of claim 20, under 35 U.S.C. 103(a), made in section 11, page 8-9 of the previous office action is withdrawn in view of the amendment to the claims.

6. The rejections of claims 26 and 27, under 35 U.S.C. 103(a), made in section 12, page 9-11 of the previous office action is withdrawn in view of the amendment to the claims.

7. The rejections of claims 24 and 60, under 35 U.S.C. 103(a), made in section 13, page 11-12 of the previous office action is withdrawn in view of the amendment to the claims.

Claim Objections

8. Claim 1 is objected to because of the following informalities: The claim does not have the proper punctuation at the end of a claim, the claim lacks punctuation at the end. Appropriate correction is required.

9. Claim 63 objected to because of the following informalities: claim 63 recites “according to claim 55, wherein wherein said second...”. It appears that the claim should only have one “wherein” recited unless there is missing text between the two “wherein”. For the purpose of

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this examination, the claim is interpreted to have only one “wherein” phrase. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 57 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Claim 57 recites the limitation "said nucleic acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 57 depends from claim 55, which does not recite a nucleic acid, the claim only recited biological macromolecules. Appropriate correction is required.

(b). Claim 62 recites “wherein said first filter one or more materials selected from the group...”. The claim lacks a transitional phrase between filter and one or more materials. For the purpose of examination, the claims are interpreted to comprise open claim language for the transitional phrase.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66, are rejected under 35

U.S.C. 102(b) as being anticipated by Jones (PCT WO95/02049). Jones teaches a method of separating biological compounds from cells by filtration using two filters with increasing pore size in the direction of sample flow.

With regard to claim 1, Jones (WO95/02049) teaches a method of purifying DNA (biological macromolecule) from *E. coli* bacterial culture (biological sample) by passing the cells through a 1 μ m filter followed by a 20 μ m filter (page 22, 1st full paragraph). Jones et al. teaches that the method can be used for genomic DNA (see page 4, 1st paragraph).

With regard to claim 2, Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell suspension to form a cell lysate containing nucleic acid and applying the cell lysate to a filter to remove unwanted cells and cell debris (page 2, 4th full paragraph).

With regard to claims 3-5, Jones teaches that any cell producing a target compound may be used in their invention. Jones defines a “cell” to encompass bacterial cells, cells from higher organisms for example blood cells, phage particles, and other cell types or organelles which contain the target compound and may require some form of lysis step to release it (page 3, 4th full paragraph). The cells are lysed prior to applying to the first filter (page 2, 4th full paragraph).

With regard to claims 6-11, Jones teaches that the target compound to be separated may comprise nucleic acid (instant claim 6), protein, or other desired compounds, in particular purifying recombinant proteins and antibodies (instant claim 7)(page 2, 2nd and 3rd paragraph).

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Jones further teaches that RNA or DNA may be purified using this invention (page 5, 2nd paragraph) (instant claim 8-11).

With regard to claims 16-18, Jones teaches the use of two filter layers to purify DNA from bacterial cells, with the first filter having 1 μm pore size and the second filter having 20 μm pore size (instant claims 16-18) (page 22, 1st full paragraph).

With regard to claims 21-25 and 27, Jones teaches the use of a first filter that retains unwanted cells and cell debris (instant claim 21), that is made of any material that can tolerate the reagents such as cellulose acetate (acetylated cellulose) (instant claim 24 and 25) and is no greater than 50 μm in pore size and no smaller than .2 μm (instant claim 22-23) (page 6, 1st full paragraph). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 24). Jones teaches that the first filter is no greater than 50 μm in pore size and no smaller than .2 μm (see page 6, 1st paragraph) and the second filter is a 20 μm pore size (see page 22, 1st full paragraph) (instant claim 27).

With regard to claim 28 and 29, Jones teaches the method of a membrane filter that is placed inside the column (tube) (instant claim 29) and has a cylindrical shape (instant claim 28) (page 11, last paragraph, figure 1 and figure 2).

With regard to claims 30-31, Jones teaches the method of lysing a cell suspension to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA by using a filtration method of increasing pore

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sizes of two filters using a 1 μ m filter followed by a 20 μ m filter and promoting the flow of lysate through the filters by positive pressure (page 22, 1st full paragraph).

With regard to claim 55-57 and 61-63, Jones teaches the method of lysing a cell suspension from *E. coli* (natural source) to form a cell lysate, applying the cell lysate to a filter to remove unwanted cells and cell debris, followed by contacting the filtered lysate with a solid phase matrix, separating the resultant filtered lysate from the matrix, and eluting the nucleic acid from the matrix (page 2, 4th full paragraph). Jones teaches the method of purifying plasmid DNA (instant claim 57) by the method of increasing the pore sizes of the filters (instant claim 55), by using a 1 μ m cellulose acetate filter followed by a 20 μ m PTFE filter (instant claim 61-62) and promoting the flow of lysate through the filters by positive pressure (instant claim 56) (page 22, 1st full paragraph and Table 1, page 21). Jones teaches that for a nucleic acid, the filter is typically glass or resin based and can bind the nucleic acid such as borosilicate glass (see page 6, 2nd paragraph) (claim 63).

With regard to claim 66, Jones et al. teaches two filters that have the inherently property of shearing genomic DNA, as evidenced by applicant's own specification (see page 13, last paragraph to page 14, 1st line).

Response to Arguments

14. The response traverses the rejection, on page 11-12 of the response mailed 09/23/2005. The response asserts that the present invention discloses a filtration apparatus comprising 2 filters with a first filter directly on top of a second filter so that the first filter is contacted with a sample before the second filter and Jones discloses two filters separated by a conduit and a

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chamber, thus the present claims are novel over Jones. This response has been thoroughly reviewed but not found persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., first filter directly on top of a second filter) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 1 recites a method "comprising" a filtration apparatus with a first filter on top of a second filter in which the first filter is contacted with the biological macromolecules before the second filter, however the claim does not require nor recite that the first filter is directly on top of the second filter. Furthermore, the transitional phrase "comprising", as recited in the MPEP, 2111.03 [R-3], The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.). The instant pending claims does not exclude additional elements, such as two filters separated by a conduit and chamber as taught by Jones et al. Therefore, Jones anticipates the claimed invention. For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

15. No claims are allowable.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571)272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

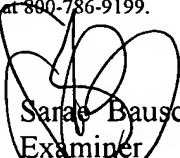
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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